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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,544	03/17/2004	Kazuhisa Fukushima	042187	2323
38834 7590 08/09/2007 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			EXAMINER SISSON, BRADLEY L	
			ART UNIT 1634	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,544	Applicant(s) FUKUSHIMA, KAZUHISA	
	Examiner /Bradley L. Sisson/	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 July 2007 has been entered.

Election/Restrictions

2. Claims 4-6 and 9-11 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02 August 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-3, 7, and 8 have been amended so to recite partitioning an electrophoretic medium into multiple “buffer chambers.” A text search of the original disclosure fails to find any instance where the expression “buffer chamber” has been used, much less an instance where it was used in the context presented in the newly amended claims.

5. A review of the response of 3 July 2007 fails to find any instance where applicant has identified a location in the original disclosure for this new limitation.

6. A review of the amendment of 23 July 2007 has also failed to identify any statement by applicant that no new matter has been added by way of said amendment.

7. For the above reasons, and in the absence of convincing evidence to the contrary, the amendment is deemed to comprise new matter. Accordingly, claims 1-3, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1-3 and 7 are indefinite with respect to just what constitutes the metes and bounds of a “buffer chamber.”

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11. Claims 1, 2, and 7 are confusing as a result of the amendment to same. As presently worded, the method requires “partitioning a container into a first buffer chamber.” It is less than clear as to how one is to fashion a “buffer chamber” when the “partition” is a filter, which can be a membrane that may be planar. If, in the alternative, one is to fashion a true chamber, which is closed on all sides, it is unclear how the biopolymer, which is trapped by the “filter” is to pass into and through the filter and on into a second chamber, when the very nature of the filter caused the biopolymer to be trapped in the first instance.

12. Additionally, it is not clear as to how the process of partitioning is to relate to the following clause- “initially containing said target biopolymer and other biopolymers.” Does the step of partitioning have to result in some actual, constructive material, or can it be virtual, e.g., a zone or region delineated by an automated control device which in the physical sense is not separated from the?

13. Claim 3, which depends from claim 2, fails to overcome this issue and is similarly rejected.

14. Applicant is urged to consider adding additional method steps such that the intended end result is actually obtained.

15. Claim 7 is indefinite where in line 12 is written, “said partition.” Upon review of the claim it is noted that there are at least three different partitions. It is unclear which partition applicant is referencing in this particular instance. Claim 8, which depends from claim 7, fails to overcome this issue and is similarly rejected.

Response to argument

16. At page 9 of the response received 23 July 2007, applicant’s representative states in part:

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17. Additionally, Office Action states that it is unclear if the "other biopolymers" also would move into the third solution when, for example, they both have the same size/mass/charge. In response, Applicants respectfully clarify the preamble of each of claims 1, 2 and 7 recites a difference in size or charge. Thus, the claims do not encompass such a situation.

18. The above argument has been fully considered and has not been found persuasive for while the preamble states that the biopolymers may have certain properties, the preamble does not stipulate that the biopolymers are being separated because of these properties.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,635,045 (Alam).

21. Alam discloses a method of separating nucleic acids from other biopolymers. As disclosed therein, biopolymers are caused to migrate through a gel (applicant's partition) via electrophoretic force. A band of gel can be excised, and placed into a second chamber, wherein the biopolymer can be eluted collected, therein separating the target biopolymer (e.g., nucleic acids) from the buffer in the second chamber.

Claim Rejections - 35 USC § 102/103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,009,759 (Serwer et al.).

25. For purposes of examination, the term "solution" has been construed to encompass solution, regardless of viscosity. As such, the term has been construed as encompassing gels used in gel electrophoresis. The term "partition" has been construed as encompassing not only pillar arrays, and filters but also gels.

26. Serwer et al., teaches developing and using both horizontal and vertical gels that have gradients of pore sizes. The differences in pore sizes may be abrupt or may be that found in a gradient, where an infinite number of degrees of separation can be developed. The myriad differences on pore sizes are deemed to meet the limitation of first second, and third solutions. The portions of the gradient where the target biopolymers are slower to move, and where they

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may eventually be trapped, are deemed to meet the limitation of applicants first and second "partition" as the target biopolymers are removed/separated/portioned from the other biopolymers.

27. As disclosed by Serwer et al., a mixture of biopolymers (e.g., nucleic acids or proteins) may be added/introduced into a gel, and then subjected to an electrophoretic force.

28. In view of the above remarks, the method of claims 1-3 is deemed disclosed, or in the alternative, rendered obvious over the disclosure of Serwer et al.

29. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as obvious over US Patent 5,635,045 (Alam) in view of US Patent Application Publication 2006/0127942 (Straume et al.).

30. See above for the basis of the rejection as it pertains to the disclosure of Alam.

31. Alam has not been found to disclose the use of magnetic beads that are attached to biopolymers.

32. Straume et al., teach at length how magnetic beads can be coupled to any of a variety of biopolymers, including nucleic acids and proteins, and can be used to separate the bound biopolymer from other components in a sample.

33. Straume et al., page 12, disclose the use of beads in an electrophoretic medium, and that the beads can be coupled to nucleic acids.

34. Paragraph [0126] teaches that magnetic beads, when coupled to DNA, are able to move through a medium in response to electrophoretic force.

35. Straume et al., page 13, bridging to page 14, teaches separation of DNA from magnetic beads.

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36. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods of Straume et al., with that of Alam, as both Alam and Straume et al., disclose isolation of biopolymers that have been caused to pass through various regions/chambers of an electrophoretic medium.

37. Said ordinary artisan would have been motivated to incorporate the method of Straume et al., into that of Alam as such would have allowed for the application of a magnetic force, and therein take advantage of the speedy movement of magnetic beads to a defined area, and therein enhance the isolation of a biopolymer from the electrophoretic buffer.

38. As en above, the elements disclosed by both Alam and Straume et al., are to function in the manner disclosed, and are to result in the same end point- the isolation of a biopolymer from a larger sample. In view of the detailed guidance, said ordinary artisan would have had a most reasonable expectation of success.

39. For he above reasons, and in the absence of convincing evidence to the contrary, claims 7 and 8 are rejected under 35 U.S.C. 103(a) as obvious over US Patent 5,635,045 (Alam) in view of US Patent Application Publication 2006/0127942 (Straume et al.).

Response to argument

40. At page 10 of the response received 23 July 2007, argument is presented that the cited prior art (Serwer) does not disclose first, second, and third buffer chambers, as the claims have been amended so to read.

41. The above argument has been fully considered and has not been found persuasive. It is noted that the “partition” or “buffer chamber” can be a gel. There is no requirement that there be any boundary material between the portion of the gel that constitutes the “chamber” and the

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surrounding material, which can also be a gel. While Serwer may not use the term “buffer chamber” to define a region of a gel, the various regions of a gel, defined by a density gradient, are still present. Indeed, the claimed method requires that electrophoresis be conducted.

Electrophoresis involves the movement of a charged matter through a gel in response to charge and physical size, and that the biopolymers are to be moving through the electrophoretic medium, and its associated buffer.

42. To the same degree that the biopolymer is moved through the chamber and buffer, Serwer achieves the same property, as both require the movement of a biopolymer through a gel via electrophoretic force.

43. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection of claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,009,759 (Serwer et al.).

Conclusion

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner
Art Unit 1634

BLS